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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
MARCO FALCIANI, ET AL.	: EXAMINER: BASICHAS, A.
SERIAL NO: 09/807,413	:
FILED: APRIL 19, 2001	: GROUP ART UNIT: 3749
FOR: BAG FOR PRESERVING AND TRANSPORTING STERILE PRODUCTS IN POWDER FORM AND FOR FORMING SOLUTIONS OF SAID PRODUCTS IN THE BAG	:

APPEAL BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicants appeal the outstanding Final Rejection of November 7, 2005, finally rejecting each of pending claims 6, 7, 9, 10, 12, 14, 16, 18-20, 22, 23, and 25.

I. REAL PARTY IN INTEREST

The above-noted application is assigned to ACS Dobfar S.p.A., which is the real party in interest in the present application, having a place of business at Viale Addetta, 6/8/10 20067 Tribiano (MI), Italy.

II. RELATED APPEALS AND INTERFERENCES

Applicants, applicants' representative, and the assignee are not aware of any related appeals, interferences, or judicial proceedings that may be related to, directly effect or be directly effected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 6, 7, 9, 10, 12, 14, 16, 18-20, 22, 23, and 25 are pending in this application, and the rejection of each of those claims is being appealed.

Claims 1-5, 8, 11, 13, 15, 17, 21, and 24 were canceled during prosecution of the present application.

IV. STATUS OF AMENDMENTS

No Amendment was filed subsequent to the Final Rejection of November 7, 2005.

However, filed concurrently with the present Appeal Brief is a Request for Consideration of References Cited in an Information Disclosure Statement filed August 14, 2003.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The applicants of the present invention recognized that a problem exists in the current art in that until the present invention it was not possible to have a bag in which a ready to use solution could be reconstituted from a sterile product in powder form such that the sterile product in powder form could be reconstituted directly into the bag still under sterile conditions to form solutions that could then be taken out from the bag as partial portions (e.g., single doses) of the total volume of the reconstituted solution. (Substitute specification page 4, lines 5-12).

As discussed in the present specification, a bag in which a sterile product in powder form is contained and which must be completely filled with a solvent to form a solution has been realized. (Substitute specification, page 3, lines 12-14). However, the drawback with that type of device is that since the bag must be completely filled with the solvent a complete solution of the powder cannot be attained by simply shaking the bag, and therefore the bag typically requires additional devices for creating turbulence within the bag. (Substitute specification, page 3, lines 14-19). Further, since the bag is always completely filled with the solvent, the bag must always start out with the same amount of soluble sterile product in order to get the final desired concentration.

To make the explanation of the claimed invention simplified, as a concrete example imagine that a sterile product in powder form to be stored within the bag is a crystalline antibiotic to be used for reconstituting injectable solutions in which the concentration of the antibiotic material must be exactly controlled at a specified value.

Before the claimed invention was made and exploited, it was also common practice to use glass bottles containing single doses of antibiotic that was dissolved directly within the bottles by feeding water into the bottles. The thereby formed single dose solutions were then drawn into syringes to be injected into patents. Such an operation is demanding and costly, particularly at hospitals where such an operation has to be repeated a large number of times everyday. (Substitute specification, page 2, lines 17-31).

It was not believed currently possible to prepare solutions of antibiotics in bags in suitable plants to then dispatch them to hospitals, because such solutions remain unaltered for a very short time. (Substitute specification, page 3, lines 1-4).

Claims 6, 7, 9, and 10 set forth, and with reference to Figures 1-5 as a non-limiting example, an improved bag 1 such that the volume of the bag 1 is larger than the volume of the reconstituted ready to use solution after the reconstitution. (Substitute specification, page

6, lines 11-14, and page 7, lines 6-7 and 29-30). That is, in the bag 1 of the noted claims after a solvent is introduced into the bag and mixes with the soluble sterile product 10 in the bag 1, the reconstituted solution only partially fills a capacity of the bag 1. That allows the bag to be easily shaken to achieve a proper solution. (Substitute specification, page 7, lines 7-9). That also allows different quantities of soluble sterile product to be initially placed in the bag. (Substitute specification, page 7, lines 9-11). Further, a volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization. (Substitute specification, page 4, lines 5-12 and page 8, lines 8-11).

Further, the bag 1 is hermetically sealed at its periphery to define a sterile closed space and has at least one port 2, 4 also of polyolefin construction defining a passageway having two ends that open inside and respectively outside the bag 1. The passageway is closed by a pierceable membrane 6, 7 for introduction of a solvent into the bag 1 and respectively for withdrawal of the read to use solution from the bag 1.

Further, the bag 1 includes a port that has a plug 20. With that structure the reconstituted liquid can be removed by piercing a syringe port through the plug 20 and withdrawing the reconstituted solution from the bag 1. The plug 20 provides a structure such that when the syringe needle is removed the reconstituted solution in the bag 1 is not able to flow out of the bag 1. (Substitute specification, page 8, lines 8-13).

Claims 12, 14, and 16 are similar to claim 6 except that claims 12, 14, and 16 are specifically directed to a "method for preparing solutions with predetermined concentrations of soluble sterile product in powder form". According to the methods of claims 12, 14, and 16, an operation is executed for feeding an amount of solvent into the bag that is less than the capacity of the bag, and individual doses of the reconstituted solution are then removed from the bag. Further, a volume of the ready to use solution reconstituted in the bag is a multiple

of single doses of the ready to use solution directly usable for practical utilization. (Substitute specification, page 4, lines 5-12, page 8, lines 8-11). Thereby, the bag also holds a multiple of single doses of the ready to use solution directly usable for practical utilization.

Certain claims, for example dependent claims 18 and 19, depend from respective independent claims 14 and 16 and further recite that "the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag". That subject matter is noted in the specification for example at page 7, first full paragraph, indicating that the bag capacity is preferably 1.5 and 2 times the volume of the solution to be prepared in it, see also claims 7 and 10. Claims 18 and 19 recite the inverse of that feature by indicating that the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.

Claims 20, 22, 23 and 25 are similar to claims 14 and 16 except that those claims are directed to "a method for using a sterile bag...". In the methods recited in claims 20, 22, 23, and 25 an operation is still executed of feeding an amount of solvent into the bag that is less than the capacity of the bag, and an operation is then executed for removing individual doses of the reconstituted solution from the bag. That is, a volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization. (Substitute specification, page 4, lines 5-12, page 8, lines 8-11).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 6, 7, 9, 10, 12, 14, 16, 18-20, 22, 23, and 25 are pending in this application.

Claims 6-25 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. patent 5,484,431 to Scharf et al. (herein "Scharf") in view of U.S. patent 5,088,996 to Kopfer et al. (herein "Kopfer") and U.S. patent 3,647,386 to Gilford. That rejection is being appealed.

VII. ARGUMENT

The claims as currently written are believed to clearly distinguish over the applied art.

The outstanding rejection cites Scharf as the primary references, but recognizes deficiencies in Scharf, and specifically recognizing that Scharf does not recite "that the bag is 'adapted' to give with the solvent and within the bag the reconstituted ready to use solution only partially filling a capacity of the bag, the specific capacity to which the bag is filled, the bag containing multiple of single doses".[1]

With respect to the above recognized deficiencies in Scharf the outstanding rejection cites "notoriously well known" teachings in the art and the teachings in Gilford.[2] However, applicants respectfully submit the outstanding rejection is improper in not fully considering each of the positively recited claim limitations, and further even the noted combination of teachings does not fully meet all of the claim limitations.

The basis for the outstanding rejection specifically states on pages 4-6 of the Final Rejection of November 7, 2005:

> ii. As regards partially filling the bag and the claimed range, adding less than the full capacity of the bag in order to allow for room to shake is well within the knowledge and ability of one of ordinary skill in the art. It is notoriously well known that providing room in a container for greater turbulence and therefore the "sloshing" of the liquid provides for more effective dissolving of the powder in the liquid. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided for only filling the bag with less than the capacity of the bag of the ready to use solution into the inventions of Scharf in order to provide room to shake the contents of the bag. Further as regards the claimed range, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated the claimed range into the invention disclosed by the above mentioned combination, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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[1] Final Rejection of November 7, 2005, page 4, labeled paragraph c.
[2] Final Rejection of November 7, 2005, labeled paragraphs c(ii)-c(iii), pages 4-6.

> iii. As regards the bag containing multiple doses, Gilford discloses a hermetically sealed polyolefin bag for preserving and transporting sterile medication specifically for removal in plural doses. This type of arrangement and method is well known in the art for the purpose of sampling the contents by removing separate doses. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated removal in plural doses, as taught by Gilford, into the inventions disclosed by Scharf, for the purpose of sampling the contents of the bag.

In response to the above-noted basis for the rejection, applicants first submit none of the cited art teaches or suggest the features recited in each of the independent claims that:

> wherein in a volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization.

Applicants first traverse the Examiner's reliance on Gilford to disclose such a feature.

Applicants note Guilford is not directed to even a similar type of device as in the primary cited reference to Scharf. Guilford is directed to a sample processing container and is not at all directed to a bag that mixes a powdery substance with a solvent as in the primary reference to Scharf. The only motivation set forth in the Office Action to make the noted combination of teachings is "for the purpose of sampling the contents of the bag" in Scharf.[3]

However, in that regard applicants note Scharf is not directed to a sample container, in contrast to Gilford. Gilford is specifically designed to store samples that must be evaluated and therefore removed. There is no ***single dose*** considered in the device of Gilford because Gilford is not directed to storing a solution that is to be applied to a patient in dosages.

In such ways, the teachings in Gilford have no relevance whatsoever to the teachings in Scharf, and Gilford itself also does not teach or suggest removing from the bag any type of reconstituted ready to used solution in individual dose sizes. Gilford discloses only portions of a sample, but not even in ***individual dose sizes***. It would be non-sensical in Gilford to

[3] Final Rejection of November 7, 2005, top of page 6.

even consider removing solutions in individual dose sizes because Gilford is not directed to storing a solution to be provided to a patient as a dosage.

In that respect, the basis for the outstanding rejection again does not even appear to proper consider the word "dose". Webster's New College Dictionary defines a dose as "a specified amount of a therapeutic agent prescribed to be taken at one time or at stated intervals".[4] Clearly Gilford does not teach or suggest anything similar to a dose. Removing a sample as in Gilford is clearly not a dose. Thus, clearly Gilford does not disclose or suggest forming in the bag "multiple single doses", as now recited in each of the claims.

Moreover, applicants note none of the cited art even recognizes benefits achieved in the present invention with respect to the above-noted feature.

In the present invention, by designing a bag to be only partially filled, different numbers of dosages of ready to use solution can be made and stored in the bag. That is, the structure of the claimed bag allows different amounts of powder to be initially placed in the bag, and combining that with the fact that different amounts of solutions can be placed in the bag (because of the oversizing of the bag), multiple doses of the ready to use solution can be reconstituted in the bag. As an example, based on the amount of sterile powder initially placed in the bag and the amount of solvent introduced into the bag, the bag can contain 1, 5, 10, etc., dosages of the ready to use solution, which can be easily distributed.

As discussed in the present specification, prior to the claimed invention being made and exploited it was common practice to use glass bottles each containing a single dose of antibiotic that was dissolved directly within a bottle by feeding water into the bottle. The thereby formed single dose solution was then drawn into a syringe to be injected into patients. Such an operation is demanding and costly, particularly in hospitals where such an operation has to be repeated a large number of times everyday.

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[4] A copy of that definition from the noted dictionary is attached hereto in the Evidence Appendix.

The present invention can overcome such drawbacks by allowing a single insertion of the proper amount solution into a bag containing a specific multiple number of doses of a powder when filled with the specific amount of solution. Thereby, in the present invention after that initial filling of the solution into the bag a healthcare provider, as an example, can then remove single dose portions from the reconstituted ready to use solution from the bag. Such features are not addressed by any of the cited art.

In such ways, the Examiner's reliance on the teaching in Gilford to meet the claim limitations directed to "wherein a volume of the ready to use the solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization", is believed to be improper. Such a feature is recited in each of the claims, and is believed to clearly distinguish over the applied art.

Moreover, none of the cited art even addresses such a feature. As noted above, Gilford is clearly unrelated to any even similar features.

With respect to the other deficiency of the admitted art as to partially filling the bag by adding less than a full capacity of the bag, the position that such is well "within the knowledge and ability of one of ordinary skill in the art" is traversed.

With respect to that feature, Applicants first note the outstanding rejection is clearly improper in not setting forth a proper *prima facie* case of obviousness.

As noted in M.P.E.P. § 2143:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicants' disclosure.

With respect to the above-noted feature of the bag being only partially filled the outstanding rejection has clearly not set forth a proper *prima facie* case of obviousness.

First, there is no suggestion or motivation in any applied reference to add less fluid than the full capacity of the bag. Second, there is no indication that utilizing such a feature would provide any expectation of success or benefit in the device of Scharf, and in fact as discussed further below applicants respectfully submit such a feature is not beneficial to the teachings in Scharf. Also, clearly the applied prior art references themselves do not teach or suggest such features. Thus, none of the criteria noted above to establish a proper *prima facie* case of obviousness has been set forth with respect to the claims.

A significant benefit of the structure of the claimed invention is that it allows different quantities of soluble, sterile product to be initially placed in a bag. In the device of Scharf cited as the primary reference for the rejection, the bag is at least substantially filled with an amount of solvent, and thus must always have the same initial amount of powder product therein to achieve a desired concentration. In contrast, in the claimed invention, since the bag is designed to be only partially filled, a different amount of sterile product can be introduced into the bag.

In the device of Scharf, a quantity of the powder product provided in the bag is initially specifically selected. By only partially filling the bag in Scharf without making any further adjustments the desired appropriate concentration would not be achieved.

Applicants also note that what the Examiner has stated as "notoriously well known" is a feature that the Examiner has not cited in any applied prior art reference. The Examiner has consistently maintained the position that only partially filling the bag was "notoriously well known".

However, what the outstanding rejection disregards as "notoriously well known" is ***contrary to what is actually taught in the applied references***.

In further detail, the applied art to Scharf discloses that when a solution has to be reconstituted within a bag containing a fixed, predetermined amount of sterile product in powder form, the bag must be filled with the solvent. That is evident from disclosure in Scharf at column 8, line 62, column 9, line 23, column 6, lines 48-51 and tables in column 7 and column 8 which indicate the total volume of the solution corresponds to the volume--one liter--of the bag. In further detail at column 8, line 62, Scharf specifically indicates "the bag is allowed to ***fill***" (emphasis added); at column 9, lines 22-23 Scharf states "filling will take approximately ten minutes, allow bag to ***fill***" (emphasis added). In the tables in columns 7 and 8 Scharf discloses filling a one liter bag with one liter of solution.

In such ways, what the Office Action indicates as "the notoriously well known" is actually contrary to the disclosure in Scharf. Given that Scharf discloses filling a bag, it is clear that it would not have been obvious to one of ordinary skill in the art to modify Scharf to not operate in that manner, particularly as reference has been cited to even suggest not completely filling a bag.

The claims are directed to storing a soluble solid product within a bag whose capacity is larger than the volume of the solution to be reconstituted therein. With the use of such a large bag, there is no need for the bag to have special shapes or include special devices to ensure proper solution of the soluble solid product in a solvent because the solid product can be quickly and completely dissolved by simply vigorously shaking the bags.

Obviously, when utilizing such a bag as claimed it is necessary to exactly measure the amount of solvent to be fed into the bag containing a measured amount of soluble solid compound. However, applicants submit the benefits of the claimed invention overcome such a drawback as it is a simple, quick operation to introduce a desired dose volume of solvent into a bag, while it is of great practical importance to have the possibility of completely and quickly dissolving a soluble product originally stored in the bag.

Further, what is considered in the Final Rejection to be "notoriously well known" would actually result in a drawback in the device of Scharf. Specifically, in that device, by completely filling the bags therein, it is not necessary to measure a volume of a solvent to be injected into the bags. Instead, the bags must just be completely filled.

In contrast to the teachings in Scharf, the claimed invention requires an extra step of properly measuring an amount of solvent to be introduced into the bag since the bag is not completely filled with the solvent. However, the applicants believe that the benefits of the present invention outweigh that inconvenience.

The outstanding Office Action maintains the rejection apparently utilizing a definition of dose as "a portion of a substance added during a process".[5] Applicants respectfully submit such a reliance is completely improper as it ignores the disclosure of the present specification. That is, the present specification does not at any point indicate that a dose can be a portion of a substance added during a process, but is always directed to substances removed from a bag. For example at page 4, lines 10-12 the substitute specification refers to a bag storing a solution that "can be easily, quickly and safely ***withdrawn in order to be used ... to supply a plurality of single individually usable doses of the same solution***, for example for filling a plurality of syringes". At page 8, lines 8-11 of the substitute specification it is disclosed that "[i]f desired, individual doses of antibiotic solution can be ***withdrawn*** through the port 4". Thus, the specification makes it clear that the definition of a dose is not the Examiner's apparent definition, which is the entire basis for the outstanding rejection.

The outstanding rejection also now apparently additionally cites U.S. patent 5,000,314 to Fuller et al. (herein "Fuller") and U.S. patents 6,695,901 and 6,352,585 to Diesso to apparently disclose leaving room at the top of a bag to aid in mixing. In that respect

[5] Final Rejection of November 7, 2006 pages 6-7, labeled paragraph 8.

applicants first note none of those references even disclose the features discussed above directed to removing individual doses from a bag.

Also, it is unclear if the Examiner is actually trying to make a rejection additionally citing Fuller or either of the references to Diesso, and if that is the case such a rejection should have been made, but has not. In any event, applicants note those references do not appear to be remotely relevant to the claimed features or the other cited references, and it is unclear on what basis the Examiner would try to attempt to combine such teachings. In any event, the reliance upon those other teachings is believed to be completely improper.

In such ways, applicants respectfully submit that clearly independent claims 6 and 9, and the claims dependent therefrom, patentably distinguish over the applied art, and that therefore claims 6-11 are allowable.

Claims 12-14, 16, 18-20, 20, 23, and 25

Moreover, applicants draw attention to the method claims that also require a specific further operation related to the above-noted feature of "removing from the bag the reconstituted ready to use solution in individual dose sizes". Such features clearly further distinguish over the applied art, and have not even been addressed in the Office Action.

Claims 7, 10, 18, 19, 23, and 25

Applicants also respectfully submit the outstanding rejection has not properly considered certain features in the dependent claims, such as "the capacity of the bag is between 1.5 and 2 times a volume of the of the ready to use solution... reconstituted in the bag" as recited in claims 7 and 10, and "the feed amount of solvent is 2/3 to1/2 of the capacity of the bag" as recited in claims 18, 19, 22, and 25.

The rejection summarily dismisses that feature as "discovering the optimal workable ranges" which "involves only routine skill in the art."[6] However, applicants traverse that position.

More particularly, it is only applicants of the present invention that have recognized expanding a capacity of a bag relative to solvents introduced therein. Further, since Scharf merely discloses completely filling a bag it is unclear how or why significantly limiting the filling of a bag could be considered an optimal workable range.

Applicants also note that it is usually with precision that a bag must be filled in devices such as in Scharf to ensure that the reconstituted solvent has the appropriate concentration. Clearly in medical applications having an improper concentration is a significant problem. Thus, the rejection is clearly improper in summarily dismissing the capacity of the bag relative to the amount of solvent as in the claims, as such a feature must be precisely controlled in the noted references to Scharf.

For these foregoing reasons, applicants respectfully submit that each of dependent claims 7, 10, 18, 19, 22, and 25 even further distinguish over the applied art, and that those claims are even further allowable.

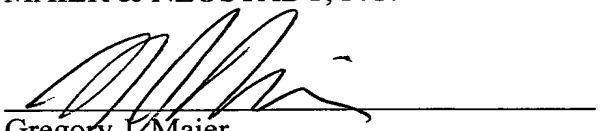
[6] Final Rejection of November 7, 2005, page 5, labeled paragraph c(ii).

For the foregoing reasons, applicants respectfully submit each of the claims as currently written patentably distinguishes over the combination of teachings of Scharf and Kopfer further in view of Gilford.

Thereby in view of these foregoing comments, applicants respectfully submit the claims as currently written are distinguishable over the applied art, and that therefore the outstanding rejection must be REVERSED.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



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VIII. CLAIMS APPENDIX

Claim 1-5 (Canceled).

Claim 6 (Previously Presented): A bag for preserving and transporting a soluble sterile product in powder form and for reconstituting in the bag a ready to use solution with a predetermined concentration of the sterile product,

the bag being of polyolefin construction;

the bag being hermetically sealed at its periphery to define a sterile closed space and having at least one port also of polyolefin construction defining a passageway having two ends that open inside and respectively outside the bag, the passageway being closed by a pierceable membrane for introduction of a solvent into the bag and respectively for withdrawal of the ready to use solution from the bag,

wherein the bag contains an amount of the sterile product in powder form adapted to give with the solvent and within the bag the reconstituted ready to use solution only partially filling a capacity of the bag,

wherein the at least one port of the bag is plugged by a plug, the plug configured to receive a syringe port through the plug to remove the reconstituted ready to use solution from the bag, and

wherein a volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization.

Claim 7 (Previously Presented): A bag according to claim 6, wherein the amount of the sterile product in powder form enclosed within the bag is such that the capacity of the bag is between 1.5 and 2 times a volume of the ready to use solution with a predetermined concentration of the sterile product reconstituted in the bag.

Claim 8 (Canceled).

Claim 9 (Previously Presented): A sealed bag constructed of flexible polyolefin material and configured to contain a ready to use solution reconstituted in the sealed bag by introducing within the sealed bag originally containing a dosed amount of a soluble sterile product in powder form an amount of solvent adapted to give the ready to use solution a desired concentration of the sterile product, wherein a capacity of the sealed bag is larger than a volume of the ready to use solution after the ready to use solution is reconstituted in the sealed bag, and wherein the volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization.

Claim 10 (Previously Presented): A bag according to claim 9, wherein a capacity of the bag is between 1.5 and 2 times the volume of the ready to use solution reconstituted in the sealed bag.

Claim 11 (Canceled).

Claim 12 (Previously Presented): A method for preparing solutions with predetermined concentrations of soluble sterile product in powder form enclosed and sealed within a sterile bag constructed of flexible polyolefin materials, comprising:

feeding into the bag, containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, an amount of solvent adapted to reconstitute a ready to use solution with a desired concentration of the sterile product, a capacity of the bag being larger than a volume of the ready to use solution after the

ready to use solution is reconstituted in the bag, and wherein the volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization; and

removing from the bag the reconstituted ready to use solution in individual dose sizes.

Claim 13 (Canceled).

Claim 14 (Previously Presented): A method for preparing solutions with predetermined concentrations of soluble sterile product in powder form enclosed and sealed within a sterile bag constructed of flexible polyolefin materials, comprising:

feeding into the bag, containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, an amount of solvent adapted to reconstitute a ready to use solution with a desired concentration of the sterile product such that the fed amount of solvent is less than a capacity of the bag, and wherein a volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization; and

removing from the bag the reconstituted ready to use solution in individual dose sizes.

Claim 15 (Canceled).

Claim 16 (Previously Presented): A method for preparing solutions with predetermined concentrations of soluble sterile product in powder form enclosed and sealed within a sterile bag constructed of flexible polyolefin materials, the bag containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, comprising:

feeding into the bag an amount of solvent adapted to reconstitute a ready to use solution with a desired concentration of the sterile product, such that the fed amount of solvent is less than a capacity of the bag and such that a capacity of the bag is larger than a volume of the ready to use solution after the ready to use solution is reconstituted in the bag, and wherein the volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization; and

removing from the bag the reconstituted ready to use solution in individual dose sizes.

Claim 17 (Canceled).

Claim 18 (Previously Presented): A method according to claim 14, wherein the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.

Claim 19 (Previously Presented): A method according to claim 16, wherein the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.

Claim 20 (Previously Presented): A method for using a sterile bag constructed of flexible polyolefin materials containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, comprising:

feeding into the bag, containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, an amount of solvent adapted to reconstitute a ready to use solution with a desired concentration of the sterile product such that the fed amount of solvent is less than a capacity of the bag, and wherein a volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization; and

removing from the bag the reconstituted ready to use solution in individual dose sizes.

Claim 21 (Canceled).

Claim 22 (Previously Presented): A method according to claim 20, wherein the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.

Claim 23 (Previously Presented): A method for using a sterile bag constructed of flexible polyolefin materials, the bag containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, comprising:

feeding into the bag an amount of solvent adapted to reconstitute a ready to use solution with a desired concentration of the sterile product, such that the fed amount of solvent is less than a capacity of the bag and such that a capacity of the bag is larger than a volume of the ready to use solution after the ready to use solution is reconstituted in the bag, and wherein the volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization; and

removing from the bag the reconstituted ready to use solution in individual dose sizes.

Claim 24 (Canceled).

Claim 25 (Previously Presented): A method according to claim 23, wherein the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.

IX. EVIDENCE APPENDIX

Attached please find the definition of the term "dose" from Webster's New College Dictionary, Copyright 2001.

X. RELATED PROCEEDINGS APPENDIX

None.

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Webster's II

New College Dictionary

Houghton Mifflin Company
Boston • New York

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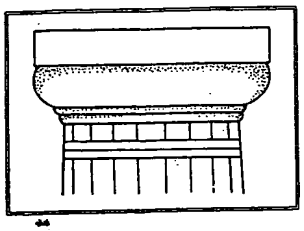
...for wiping the shoes. 2. *Slang.* One who unprotestingly allows mistreatment by others.
...nail (dôr'nāl', dōr'-) *n.* A large-headed nail once used as a stud ... **—dead as a doornail.** Undoubtedly dead.
...post (dôr'pōst', dōr'-) *n.* A doorjamb.
...prize *n.* A lottery prize awarded to the holder of a ticket purchased at or before a function.
...sill (dôr'sĭl', dōr'-) *n.* The threshold of a doorway.
...step (dôr'stĕp', dōr'-) *n.* A step leading to a door.
...stop (dôr'stŏp', dōr'-) *n.* 1. A wedge inserted beneath a door to hold it open at a desired position. 2. A weight or spring that prevents a door from slamming. 3. A rubber-tipped projection attached to a wall to protect it from the impact of an opening door.
...-to-door (dôr'tə-dôr', dōr'tə-dōr') *adj.* Making or being unsolicited calls from one house to another in an area <a *door-to-door* salesman> **—door'-to-door'** *adv.*
...way (dôr'wā', dōr'-) *n.* The entrance to a room or building.
...woman (dôr'wo͝om'ən, dōr'-) *n.* A woman employed to attend the entrance of a hotel, apartment house, or building.
...yard (dôr'yärd', dōr'-) *n.* A yard in front of the door of a house.
doo-zie or **doo-zie** (do͞o'zē) *n., pl.* **-zies.** [Poss. blend of DAISY and DUESENBERG, a luxury car of the late 1920's and 1930's.] Something extraordinary or bizarre.
dopa (dō'pə) *n.* [Contraction of E. *dihydroxyphenylalanine.*] An amino acid, $C_9H_{11}NO_4$, that is converted to dopamine in the blood-stream and used to treat Parkinson's disease.
dopamine (dō'pə-mēn') *n.* [DOP(A) + AMINE.] A monoamine neurotransmitter that is a carboxylated form of dopa and is essential to normal nerve activity.
dopant (dō'pənt) *n.* [DOP(E) + -ANT.] A small quantity of a substance, as phosphorus, that is added to another substance, as a semiconductor, to alter the latter's properties.
dope (dōp) *n.* [Du. *doop,* sauce < *doopen,* to dip.] 1. A viscid substance or liquid, esp. a lubricant such as axle grease or an absorbent material such as the nitroglycerin used to make dynamite. 2. A preparation resembling varnish formerly used to protect, waterproof, and tighten the cloth surfaces of airplane wings. 3. *Informal.* A narcotic, esp. one that is addictive. 4. A narcotic used to alter the performance of a racehorse. 5. *Slang.* A very stupid person. 6. *Slang.* Factual, esp. confidential information. — *v.* **doped, dop·ing, dopes.** — *vt.* 1. To add dope to. 2. *Informal.* To administer a narcotic to. 3. *Informal.* To figure out (an outcome or puzzle). 4. *Informal.* To make a rough sketch of. — *vi. Informal.* To take drugs. **—dop'er** *n.*
dope sheet *n. Slang.* A publication giving information on the horses running in the day's races.
dope·ster (dōp'stər) *n.* One who analyzes and predicts future events, as in sports or politics.
dopey *also* **dop·y** (dō'pē) *adj.* **dop·i·er, dop·i·est** *Slang.* 1. Lethargic from or as if from drugs. 2. Stupid. 3. Foolish.
dop·pel·gäng·er *or* **dop·pel·gang·er** (dŏp'əl-gĕng'ər, dōp'əl-) *n.* [G. : *doppel,* double + *gänger,* goer < *gehen,* to go.] A double of a living person, esp. one that haunts its own counterpart.
Doppler (dŏp'lər) *adj.* Of, relating to, or utilizing the Doppler effect in Doppler radar.
Doppler effect (dŏp'lər) *n.* [After Christian Johann *Doppler* (1803-53).] An apparent change in the frequency of waves, as of sound or light, when the source and observer are in motion relative to one another, the frequency increasing when the source and observer approach one another and decreasing when they move apart.
Doppler radar *n.* Radar that uses the Doppler effect to measure velocity.
dopey (dō'pē) *adj. var. of* DOPEY.
Dorado (də-rä'dō) *n.* A constellation of the Southern Hemisphere between Tucana and Pictor.
dor·bee·tle (dôr'bēt'l) *n.* [Obs. *dor,* a buzzing bee or beetle (< ME *dora* < OE *dora*) + BEETLE.] An Old World dung beetle, *Geotrupes stercorarius,* that makes a droning sound in flight.
Dorcas society (dôr'kəs) *n.* [After *Dorcas,* a Christian woman of the 2nd cent. A.D.] A women's auxiliary group, often sponsored by a church, that provides clothes for the poor.
Dor·i·an (dôr'ē-ən, dōr'-) *n.* One of a Hellenic people that invaded Greece around 1100 B.C. and remained culturally and linguistically distinct within the Greek world, esp. in Sparta, Corinth, and Argos. — *Dor'i·an adj.*
Doric (dôr'ĭk, dŏr'-) *n.* [Lat. *Doricus* < Gk. *Dorikos* < *Doris,* a region of ancient Greece.] A dialect of ancient Greek spoken in the Peloponnesus, Crete, certain of the Aegean islands, Sicily, and in southern Italy. — *adj.* 1. Of, pertaining to, typical of, or designating Doric. 2. Designating or in the style of the Doric order.
Doric order *n.* The oldest and simplest of the three orders of classical Greek architecture, marked by heavy, fluted columns having no base and plain saucer-shaped capitals.



Doric order

Dor·king (dôr'kĭng) *n.* [After *Dorking,* a town in England.] A domestic fowl of a breed with a heavy body, raised mainly for the table.
dorm (dôrm) *n. Informal.* A dormitory.
dor·mant (dôr'mənt) *adj.* [ME *dormaunt* < OFr. *dormant* <pr.part. of *dormir,* to sleep < Lat. *dormire.*] 1. Asleep or inactive. 2. Latent but capable of being activated <"a harrowing experience which . . . lay *dormant* but still menacing" — Charles Jackson> 3. Temporarily quiescent, as a volcano. 4. *Biol.* Being in a relatively inactive or resting condition in which some processes are slowed down or suspended. **—dor'man·cy** *n.*
dor·mer (dôr'mər) *n.* [OFr. *dormeor,* bedroom < *dormir,* to sleep < Lat. *dormire.*] 1. A window set vertically in a small gable projecting from a sloping roof. 2. The gable holding a dormer.
dor·mie (dôr'mē) *adj. var. of* DORMY.
dor·min (dôr'mĭn) *n.* [DORM(ANCY) + -IN.] Abscisic acid.
dor·mi·to·ry (dôr'mĭ-tôr'ē, -tōr'ē) *n., pl.* **-ries.** [Lat. *dormitorium* < *dormitorius,* of sleep < *dormire,* to sleep.] 1. A room furnished with beds for a number of persons. 2. A structure for housing a number of persons, as at a school. 3. A suburban community whose residents commute to a nearby metropolis for employment and recreation.
dor·mouse (dôr'mous') *n.* [ME *dormowse.*] Any of various small, squirrellike Old World rodents of the family Gliridae.
dor·my *also* **dor·mie** (dôr'mē) *adj.* [Orig. unknown.] Ahead of an opponent by as many holes in a golf match as remain to be played.
dor·nick[1] (dôr'nĭk) *n.* [ME *dornick,* after *Doornik* (Tournai), Belgium.] A coarse damask cloth.
†dor·nick[2] (dôr'nĭk) *n.* [Perh. of Celtic orig.] *Regional.* A small chunk of rock : STONE.
do·ron·i·cum (də-rŏn'ĭ-kəm) *n.* [NLat. < Ar. *dorūnaj.*] A plant of the genus *Doronicum,* which includes the leopard's-bane.
dors– *pref. var. of* DORSO-.
dor·sad (dôr'săd') *adv. Anat.* In the direction of the back.
dor·sal (dôr'səl) *adj.* [LLat. *dorsalis* < Lat. *dorsualis* < *dorsum,* back.] 1. *Anat.* Of, toward, on, in, or near the back. 2. *Bot.* Of or on the outer surface, underside, or back of an organ. **—dor'sal·ly** *adv.*
dorsal fin *n.* The main fin on the dorsal surface of fishes or certain marine mammals.
Dor·set Horn (dôr'sĭt) *n.* [After *Dorset,* a county in England.] A long-horned domestic sheep of a breed with fine-textured wool.
dorsi– *pref. var. of* DORSO-.
dor·si·ven·tral (dôr'sĭ-vĕn'trəl) *adj.* Having distinct upper and lower surfaces.
dorso– *or* **dorsi–** *or* **dors–** *pref.* [< Lat. *dorsum,* back.] 1. Back <*dorsad*> 2. Dorsal <*dorsoventral*>
dor·so·ven·tral (dôr'sō-vĕn'trəl) *adj.* [DORSO- + VENTRAL.] Extending from a dorsal to a ventral surface.
dor·sum (dôr'səm) *n., pl.* **-sa** (-sə) [Lat., back.] *Anat.* 1. The back. 2. A part of an organ or appendage analogous to the back.
do·ry[1] (dôr'ē, dōr'ē) *n., pl.* **-ries.** [Mosquito *dôri,* dugout.] A small, narrow, flat-bottomed fishing boat with high sides and a sharp prow.
do·ry[2] (dôr'ē, dōr'ē) *n., pl.* **-ries.** [ME *dorre* < OFr. *doree,* gilded, fem. p.part. of *dorer,* to gild < LLat. *deaurare* : Lat. *de-* (intensive) + Lat. *aurum,* gold.] 1. The John Dory. 2. WALLEYE 3.
DOS (dŏs, dōs) *n.* [D(ISK) O(PERATING) S(YSTEM).] *Computer Sci.* An operating system that resides on a disk.
dos-à-dos (dō'zā-dō') *n., pl.* **dos-à-dos** (-dōz', -dō') [Fr. : *dos,* back + *à,* to + *dos,* back.] A sofa or carriage accommodating two people seated back to back.
dos·age (dō'sĭj) *n.* 1. a. Administration of a therapeutic agent in prescribed amounts. b. Determination of the amount to be administered. c. DOSE 1. 2. Addition of an ingredient to a substance, esp. to wine, in a specific dose.
dose (dōs) *n.* [Fr. < LLat. *dosis* < Gk. < *didonai,* to give.] 1. A specified amount of a therapeutic agent prescribed to be taken at one time or at stated intervals. 2. *Med.* The amount of radiation administered to a certain bodily part. 3. *Informal.* A portion of an experience, esp. of something unpleasant, to which one is subjected <a *dose* of misfortune> 4. An ingredient added, esp. to wine, to impart flavor or strength. 5. *Slang.* A venereal infection. — *vt.* **dosed, dos·ing, dos·es.** 1. To give a dose to, as of medicine. 2. To give or prescribe (medicine) in doses. **—dos'er** *n.*
do-si-do (dō'sē-dō') *n., pl.* **-dos.** [Var. of DOS-À-DOS.] 1. A square-dance movement in which two dancers approach each other and circle